DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
200 C Street S.W.
Washington D.C. 20204

9/1936d

Date: NOV - 9 2001

WARNING LETTER

VIA FACSIMILE AND
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: ONPLDS-03-02

Mr. R. Scot Hunter, CEO
ScienceBased Health®
300 Tamal Plaza, Suite 220
Corte Madera, California 94925
FAX: 415-927-0990

Dear Mr. Hunter:

This letter is in reference to your firm's marketing of products as dietary supplements. The Food and Drug Administration (FDA) has reviewed labeling found on your web site at the Internet address: http://www.sciencebasedhealth.com and has determined that the products **MaculaRx™** and **MaculaRx Plus™** are promoted using statements that suggest that they are intended for use in treating diseases of the eye.

The claims observed on your web site include, among others:

"MaculaRx™ and MaculaRx Plus™ are state-of-the-art, synergistic multinutrient combinations designed to address different aspects of age-related degenerative conditions of the human eye. MaculaRx™ is designed for patients diagnosed in the early stages of macular degeneration. MaculaRx Plus™ is a therapeutic formulation for patients in the later stages of macular degeneration."

"MaculaRx™ and MaculaRx Plus™ are effective tools that may help reverse symptoms of macular degeneration and other eye disorders."

Your products MaculaRx™ and MaculaRx Plus ™ would ordinarily be considered dietary supplements. Because your labeling includes statements which represent or suggest that the products are intended to be used in the cure, mitigation, treatment, or prevention of disease, the products are drugs within the meaning of section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(g)(1)(B)]. FDA has no information that your

products are generally recognized as safe and effective for the above referenced conditions and therefore, they also are "new drugs" as described in section 201 (p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally marketed in the U.S. without an approved New Drug Application from FDA as described in section 505 (a) of the Act [21 U.S.C. 355(a)].

These products are also misbranded within the meaning of section 502(a) of the Act because their labeling is false and misleading in that they suggest that there is evidence that these products are safe and effective for their intended use, when, in fact, this has not been established. These products are further misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] because their labeling fails to bear adequate directions for their intended uses.

This letter does not represent a complete review of your Internet web site nor other product labeling or promotional materials, including immediate container labels, product brochures, product catalogs, product flyers, newsletters, and advertisements. It is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

We request that you notify this office in writing within 15 days of receipt of this letter, of the specific steps you have taken or plan to take to correct the stated violations. Failure to promptly correct these violations may result in an enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Please send your reply to the Food and Drug Administration, Attention: Andrew H. Paeng, Compliance Officer, Division of Compliance and Enforcement, ONPLDS, 200 C. Street S.W., Washington D.C. 20204. If you have any questions concerning any issue in this letter, please contact Mr. Paeng at (202) 690-0437.

Sincerely yours,

/S/

John B. Foret, Jr.
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and
Dietary Supplements
Center for Food Safety and
Applied Nutrition